

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/585,474	STROPP, UDO	
	<b>Examiner</b>	<b>Art Unit</b>	
	STEVEN C. POHNERT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3, 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. <u>6/28/2010</u> .                          |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date <u>3/11/2010, 5/3/2007, 5/3/2007</u> .                           | 6) <input type="checkbox"/> Other: _____.                          |

### DETAILED ACTION

The application fails to comply with CFR 1.821(d), which states:

(d)Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

For example, tables 1 and 2 and page 32 lines 7 and 8, contains a nucleic acid sequence. Applicant is required to check the rest of the disclosure for any other nucleic acid or protein sequences and list them in a sequence listing and identify them with a proper "SEQ ID NO:".

The specification and sequence listing must be amended to bring it into sequence compliance. **For any response to this office action to be fully compliant, the response has to bring the application in compliance with sequence rules.**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II, claim 3, 5, and 6 in the reply filed on 3/11/210 is acknowledged. Claims 3 and 5 are in group I of the restriction requirement. Thus the examiner contacted applicant's representative. The representative confirmed the election of group II, methods claims.

Claims 3 and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention , there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/11/2010.

### ***Priority***

The instant application was filed 8/15/2008 and is a National stage entry of PCT/EP05/000064 filed 1/7/2005, which claims priority to European application 04000398.0 filed 1/10/2004.

### ***Claim Objections***

2. Claim 6 objected to because of the following informalities:

Claim 6 requires at least one SNP and polymorphic positions of claim 4. However, claim 4 has been canceled. Thus these limitation are being broadly interpreted as any SNP or polymorphic position for art reasons.

Further claim 6 is drawn to the primers in Table 2. The claim refers to tables. MPEP 2173.05(s) states:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience."

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 in part b) requires the primers of table 2. Claim 6 part d) requires, “wherein said primers are selected from the group comprising primers that hybridize to the polymorphic position in the human TMPT genes according to claim 4; and primers that hybridize immediately adjacent to the polymorphic positions in the TMPT genes according to claim 4. Table 2 of the specification teaches primers and probes to SNPs 1-50 and indicates the primers are labeled with F or R for the forward and reverse primers. The primers listed do not comprise any polymorphic positions and thus the claim is internally inconsistent. The probes comprise the polymorphic position. Thus it is unclear if the primers require the sequences of table 2 or the limitations of part d).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al (US Patent 5,856, 095, issued Jan 5, 1999).

Claim 6 part d) requires, “wherein said primers are selected from the group comprising primers that hybridize to the polymorphic position in the human TMPT genes according to claim 4; and primers that hybridize immediately adjacent to the polymorphic positions in the TMPT genes according to claim 4. Table 2 of the specification teaches primers and probes to SNPs 1-50 and indicates the primers are labeled with F or R for the forward and reverse primers. The primers listed do not

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comprise any polymorphic positions. The probes comprise the polymorphic position.

Thus the primers of table 2 is being given the broadest reasonable interpretation of any primer due to the conflicting limitations in the claims.

Further Claim 6 is drawn to at least one SNP and polymorphic positions of claim 4. However, claim 4 has been canceled. Thus the SNPS and polymorphic positions of claim 4 are being given the broadest reasonable interpretation of any TPMT polymorphism or position.

Evans teaches Claim 15: A diagnostic assay for determining thiopurine S-methyl-transferase (TPMT) genotype of a subject which comprises

(a) isolating nucleic acid from said subject;

(b) amplifying a thiopurine S-methyltransferase (TPMT) PCR fragment from said nucleic acid using a first and a second set of primers in a first and a second PCR reaction, respectively; wherein the first set of primers contains primer X and primer Y, and the second set of primers contains primer X and primer Z; wherein

(i) the Y primer is complementary to a region 5' to one of three point mutation sites at cDNA positions 238, 460, or 719, and includes the wild type nucleotide for said cDNA position;

(ii) the Z primer is identical to the Y primer except that instead of the wild type nucleotide, it contains the respective mutant nucleotide at the respective cDNA positions 238, 460, or 719; and

(iii) the X primer is complementary to a region 3' to the point mutation

site corresponding to primers Y and Z;

(c) amplifying the sequence in between primers X and Y and in between primers X and Z; thereby obtaining an amplified fragment in each of the first and the second PCR reactions; and

(d) visualizing the contents of the first and the second PCR reactions, thereby determining the thiopurine S-methyltransferase (TPMT) genotype of said subject.

Evans thus teaches isolating a nucleic acid from a subject, amplifying TPMT by PCR using primers that hybridize to a polymorphic position and adjacent position and determining the genotype from the amplified segment and thus anticipates the claim.

### **Summary**

No claims are allowed.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN C. POHNERT whose telephone number is (571)272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven C Pohnert/  
Primary Examiner, Art Unit 1634